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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/414,384
Filing Date: October 07, 1999
Appellant(s): CLARK ET AL.

Guy V. Tucker
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 2, 2009 appealing from the Office action mailed May 1, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,479,920	PIPER et al.	1-1996
4,227,522	CARRIS	10-1980

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 21, 24, 28, 32, 34, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Piper et al. (5,479,920).

As to Claim 21, Piper discloses a device for controlling the delivery of an aerosolized active agent to the lungs of a human patient, said device comprising a valve (24) that provides a high flow resistance of at least 0.4 (cm $H_20)^{½}$/SLM at the onset of the patient's inhalation and that subsequently opens to provide a lower flow resistance, wherein the lower flow resistance allows for a higher flow rate through the device. Regarding the high and low flow resistance limitation, Piper discloses the valve (24) is an inhalation valve that closes and enables pressure to build up above atmospheric pressure during exhalation, and opens once the pressure upon the valve drops below atmospheric pressure during inhalation. (Column 4, Lines 25-35). Inherently, the nature of the valve to operate in response to pressure effects the operation of the valve and the resistance in the valve's operation. At the point at which the user of the breathing circuit begins to inhale, the resistance within the valve would be high as the pressure within the breathing circuit would be greater than atmospheric pressure and

the valve is closed; however, subsequently as the user continues to inhale, the pressure within the breathing circuit would drop to below atmospheric pressure thus opening the valve and increasing the flow rate of the gas thru the valve.

As to Claims 24, 34, and 36, Piper discloses the high flow resistance when the valves are closed. Inherently, when the valves are closed the flow rate thru the valves are less than 15 liters per minute. Further, as addressed by Piper, during the initial stages of inhalation the pressure differential must be overcome to open the valves. Finally, regarding the values of flow rate, the flow rate of a patient's inhalation is a function of not only device but the patient's characteristics and overall health. In regards to the characteristics of the patient, the lung volumes of a neonate, child, adult, elderly and animals vary, in addition to the lung volume between genders. In regards to the overall health of a patient, if the patient suffers from a chronic lung disease such as asthma, emphysema, or COPD, the patient would not be able to provide as great of an inhalation flow rate as a healthy patient not suffering from a lung disease. Specifically regarding claim 36, at the first flow resistance the flow rate thru the device 0 liters/minute because the valves is closed; however, at the second flow rate when the valves beings to open as a result of the decreasing pressure differential the flow rate thru the device would be higher than the first flow rate.

As to Claim 28, Piper discloses a device for controlling the delivery of an aerosolized active agent to the lungs of a human patient, said device comprising a valves (24) that provides a high flow resistance at the onset of the patient's inhalation and which corresponds to a flow rate of about 15 liters per minute or less and that

subsequently opens to provide a lower flow resistance, wherein the lower flow resistance allows for a higher flow rate. Regarding the high and low flow resistance limitation, Piper discloses the valves (24) is an inhalation valves that closes and enables pressure to build up above atmospheric pressure during exhalation, and opens once the pressure upon the valves drops below atmospheric pressure during inhalation. (Column 4, Lines 25-35). Inherently, the nature of the valves to operate in response to pressures effects the operation of the valves and the resistance in the valves operation. At the point at which the user of the breathing circuit begins to inhale, the resistance within the valves would be high as the pressure within the breathing circuit would be greater than atmospheric pressure and the valves are closed; however, subsequently as the user continues to inhale, the pressure within the breathing circuit would drop to below atmospheric pressure thus opening the valves and increasing the flow rate of the gas thru the valve. Regarding the values of flow rate, the flow rate of a patient's inhalation is a function of not only device but the patient's characteristics and overall health. In regards to the characteristics of the patient, the lung volumes of a neonate, child, adult, elderly and animals vary, in addition to the lung volume between genders. In regards to the overall health of a patient, if the patient suffers from a chronic lung disease such as asthma, emphysema, or COPD, the patient would not be able to provide as great of an inhalation flow rate as a healthy patient not suffering from a lung disease.

As to Claim 32, Piper discloses a device for controlling the delivery of an aerosolized active agent to the lungs of a human patient, said device comprising a valve (24) that provides a first flow resistance at the onset of the patient's inhalation and that

subsequently opens to provide a second flow resistance, the second resistance is less than the first resistance, wherein the second flow resistance allows for a higher flow rate through the device. Regarding the first and second flow resistance limitation, Piper discloses the valve (24) is an inhalation valve that closes and enables pressure to build up above atmospheric pressure during exhalation, and opens once the pressure upon the valve drops below atmospheric pressure during inhalation. (Column 4, Lines 25-35). Inherently, the nature of the valve to operate in response to pressures effects the operation of the valve and the resistance in the valves operation. At the point at which the user of the breathing circuit begins to inhale, the resistance within the valve would be high as the pressure within the breathing circuit would be greater than atmospheric pressure and the valve is closed; however, subsequently as the user continues to inhale, the pressure within the breathing circuit would drop to below atmospheric pressure thus opening the valve and increasing the flow rate of the gas thru the valve.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 22, 23, 26, 27, 30, 31, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piper et al. (5,479,920).

As to Claims 22 and 30, Piper discloses a high flow resistance when the valves are closed during the initial stages of inhalation, but does not expressly disclose the recited resistance values. Yet, Piper discloses the operational thresholds are a function of the resistance of the valves and may be varied. (Column 6, Lines 1-4). Therefore, the ability of the valves to be opened wider would increase the flow and the ability of the valves to be closed tighter would decrease the flow; therein, creasing a result-effective variable by which the degree at which the device is opened or closed can be optimized as much as desired by the inventor. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the operational thresholds of the valves, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) and *In re Aller*, 105 USPQ 233, respectively.

As to Claim 23, Piper discloses low flow resistances when the valves are open once the pressure differential has been overcome during the subsequent stages of inhalation, but does not expressly disclose the recited resistance values. Yet, Piper discloses the operational thresholds are a function of the resistance of the valves and may be varied. (Column 6, Lines 1-4). Therefore, the ability of the valves to be opened wider would increase the flow and the ability of the valves to be closed tighter would decrease the flow; therein, creasing a result-effective variable by which the degree at which the device is opened or closed can be optimized as much as desired by the

inventor. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the operational thresholds of the valve of Piper, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) and *In re Aller*, 105 USPQ 233, respectively.

As to Claims 26, 27, 31 and 33, Piper discloses the high flow resistance, yet does not expressly disclose the length of time in which the high flow resistance is experienced. However, the length of time the high flow resistance is experienced by the patient is a function of the delivery device, the patient's characteristics and the patient's overall health, which all play a factor in the patient's ability to overcome the pressure gradient within a recited time. In regards to the delivery device, Piper discloses the operational thresholds are a function of the resistance of the valves and may be varied. (Column 6, Lines 1-4). In regards to the characteristics of the patient, the lung volumes of a neonate, child, adult, elderly and animals vary, in addition to the lung volume between genders. In regards to the overall health of a patient, if the patient suffers from a chronic lung disease such as asthma, emphysema, or COPD, the patient would not be able to provide as great of an inhalation flow rate as a healthy patient not suffering from a lung disease. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the operational thresholds of the valves, since it has been held that discovering an optimum value of a result effective

variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

5. Claims 25, 29 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piper et al. (5,479,920) in view of Carris (4,227,522).

As to Claims 25, 29 and 35, Piper discloses a low flow resistance, yet does not expressly disclose the flow resistance corresponds to a flow rate between 15 and 80 liters per minute. However, at the time the invention was made the use of breath actuated medicament delivery devices utilizing the recited flow rates was known. Specifically, Carris teaches people having differing lung capacities and strengths may generate flow rates between 30 liters per minute to 120 liters per minute for the purpose of enabling the delivery of medicament from the drug delivery device to the patient. Therefore it would have been obvious to one having ordinary skill in the art to modify the low flow resistance flow rates to incorporate the known range of patient flow rates, as taught by Carris, to ensure the actuation of the drug delivery device.

(10) Response to Argument

Appellant's arguments have been fully considered, but they are not persuasive. Appellant asserts: Piper does not disclose or teach "a valve that provides a high flow resistance of at least 0.4 (cm $H_2O)^{½}$ / SLM in the inhalation direction at the onset of the patient's inhalation". Examiner respectfully disagrees.

Piper discloses a valve (24) operating in the inhalation direction to open, where the valve (24) is disclosed as a flapper valve. (Column 4, Lines 22-25). Regarding the actuation of the valve, Piper discloses the valve will actuate to an open position when the threshold pressure is below atmospheric pressure. (Column 4, Lines 26-35). Further, Piper discloses the thresholds are a function of the resistance of the valve and can be varied in order to control actuation of the valve (Column 6, Lines 1-3).

As previously addressed in the Final Office action, mailed May 1, 2009, the transition between inhalation and exhalation is a gradual change, wherein the inhalation flow increases to a peak inhalation flow during the breathing cycle. With respect to the claimed invention, "*at the onset of inhalation"* (emphasis added) the resistance to open the valve would be greatest and result in limited flow through the valve; however, throughout the course of the inhalation cycle to the peak inhalation flow, the resistance to open the valve would lessen and result in a greater flow of gas through the valve. Further, during the second half of the inhalation cycle from peak inhalation flow to the onset of exhalation flow, the resistance to open the valve would be greater and result in limited flow through the valve. Thus, the operation of the valve with respect to patient inhalation is similar to that of a bell curve where higher inhalation flows have less resistance from the valve.

With respect to the limitation of "a high flow resistance of at least 0.4 (cm $H_2O)^{½}$ / SLM in the inhalation direction", as addressed, valve (24) is a one-way inhalation valve; thus, during exhalation, the valve (24) is closed and has a resistance of infinity. Therefore, "a*t the onset of inhalation"* (emphasis added) the threshold pressure to

actuate the valve must be overcome in order to direct the opening of the valve from a high flow resistance to a lower flow resistance at the peak inhalation flow.

Finally, with respect to Appellant's assertions of the valve of Piper, it should be noted Page 11, Lines 17-20 of Appellant's specification where Appellant has admitted a mechanical valve system may be utilized to perform the same function. Piper's flapper valve (24) is a mechanical valve system wherein the operation of the valve may be varied to control actuation of the valve. (Column 6, Lines 1-3). Therefore, as the valve of Piper is able to be actuated in the inhalation direction at desired resistances and thresholds, the valve of Piper, meets the claimed limitations of a valve which "provides a high flow resistance of at least 0.4 (cm $H_2O)^{½}$ / SLM in the inhalation direction *at the onset of the patient's inhalation*."

Thus, in light of the aforementioned reasoning the rejection of the claims has been maintained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Annette F Dixon/

Examiner, Art Unit 3771

Conferees:

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

/Greg Vidovich/

TQAS, TC 3700